Kansas Medical Assistance Program

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

July 13, 2005

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas July 13, 2005	**Members Present:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., C.M.D.; Dennis Grauer, Ph.D.; Kevin Kentfield, PharmD; Brenda Schewe, M.D.; Roger Unruh, D.O.; Kevin Waite, PharmD; Tom Wilcox, R.Ph. **SRS Staff Present:** Anne Ferguson, R.Ph., DUR Program Director; Mary Obley, R.Ph.; Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.; Deb Quintanilla, R.N.	**Representatives:** Craig Boon (ACS Heritage), Jason Crowe (ACS Heritage), Patty Laster (Genentech), Bruce Kirby (Genentech), Ann Gustafson (GlaxoSmithKline), Dr. Wayne Moore (Children's Mercy Hospital), Michael Waljie (AstraZeneca), Rhonda Clark (Purdue), Elizabeth Stoltz (Janssen), Joshua Lang (Novartis), James Dube (Purdue), Ronald Godsey (TAP), Mike Moratz (Merck), Tammy Shelor (Naplor), Patricia Solbach (Janssen), Eric Gardner (Wyeth), Tammie Capps (Purdue), Bob Twillman (KU Medical Center), Jon Snow (UCB Pharma), Dr. Kenneth Dykstra (Wichita), Jim Baumann (Pfizer)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 10:05a.m.	
II. Announcements – New DUR Board Members	• Anne introduced the new DUR Board members, Tom Wilcox, R.Ph and Kevin Kentfield, PharmD.	
III. Review and Approval of May 11, 2005, Meeting Minutes	• There were no additions or corrections to the May 2005 meeting minutes.	• A motion to approve the minutes as written was made by Dr. Waite and seconded by Dr. Schewe. The motion carried unanimously by roll call.
IV. New Business **A. Heritage** **1. Overview** **2. Updates – Pediatric Antidepressant Intervention Outcomes**	• Craig Boon (ACS Heritage) presented an overview of what tasks Heritage performs for the DUR program. • Craig presented outcome information regarding the Pediatric Psychiatric Coordination of Care intervention. Data suggests that there is no apparent cost shifting in pharmacy. There was a slight decrease in antidepressant use in pediatrics. • Craig presented the list of diagnosis codes found for the Gabapentin intervention.	

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B. Benzodiazepines – Utilization Review	• Dr Burke reviewed the reason the state decided to start covering benzodiazepines. He stated that the coverage of benzodiazepines began in January of 2005. • Anne reviewed the charts and graphs regarding benzodiazepines and sedative/hypnotics/anti-anxiety drugs. This is a very short time period to review this class of drugs and see a difference. Ambien usage appears to be remaining steady Sonata and Buspirone seem to be decreasing. Anne would like to bring this back to the March of 2006 DUR meeting and review a full years worth of data.	• Benzodiazepines will be brought back in March of 2006, so a full years worth of data can be reviewed.
C. Xolair® - PE Variability Defined **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the Xolair draft criteria forms and explained that this is brought to the DUR board due to a couple of clarifications that need to be made. Requesting the age was inadvertently left off the original criteria and there has been confusion regarding the request for PE variability. Providers have not been able to provide this information. We believe this was a typo and it should be PEF variability. Anne reviewed the articles regarding PEF variability. We either need to remove PE variability from the criteria if determined to be unnecessary or come up with a good definition for the prior authorization (PA) unit. • Dr. Burke asked what the PA unit has been doing regarding Xolair. Mary explained that this PA began in May, so when the PA unit called her stating the physicians did not know what PE variability was, Mary told them to approve if the patient met the rest of the criteria. Deb stated that we have only had 3 requests in May and they were all approved. There were 10 requests in June, 3 were approved and 7 were denied. The 7 that were denied were not denied due to the PE variability.	
2. Public Comment	• Lee Ding, PharmD (Genentech) presented information to the DUR Board regarding Xolair. Dr. Ding made two suggestions to the present criteria, combine numbers one and two due to redundancy and for number 3 on the second page add and/or documented symptomatic improvement per physician assessment. • Dr. Burke asked how difficult is it to determine a PEF variability chart. Dr. Unruh stated that you have to have the correct equipment in your office and the test has to be done 3 times and average them. There are problems with	

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Xolair – Con't	compliance, not having the correct equipment, and you have to teach the beneficiary how to use the equipment. He feels the test is cumbersome and inaccurate especially in the young and old patients. • Anne stated that she was under the impression that PEF rate was determined by a device that the beneficiary had at home called a peak flow meter. Dr. Unruh stated it is used, but it is not reliable. • Dr. Burke clarified that the question at present is PEF variability, can we define it, or should it be removed from the criteria. • Dr. Burke asked if we could have the physician use information retrieved at office visits. • Dr. Waite stated that variability is not a good indicator, thinks that it should not be included on the PA. • Dr. Unruh stated that item number 12 states that only pulmonologist, allergist, or immunologist can prescribe Xolair, this excludes primary care physicians. Have all the PAs been from required physicians. Deb stated that all the PAs are from the correct specialty physician. • Dr. Unruh stated that if we remove PEF variability, this could increase the number of PAs. Dr. Burke stated we could revisit and look at utilization. • The Board also agreed that they should combine numbers one and two, add documented symptomatic improvement per physician assessment to number four on the second page, add the requirement for age on number 1, and drop PE variability. • Dr. Schewe recommended changing number 12 to listing the specialty fields instead of asking the physician their specialty. Dr. Unruh agreed and suggested placing this at the top of the criteria. Dr. Waite recommended listing the ages that would be approved.	
3. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Schewe and seconded by Dr. Unruh to add the age requirements to number 1 on both request form and criteria, combine number one and two on the criteria, move number twelve to the top

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Xolair – Con't		and list the required physician specialties on both request form and criteria, and add documented symptomatic improvement per physician assessment to number 4 on the second page of the criteria. The motion passed unanimously by roll call.
D. Remicade® - New Indications **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the updated PA criteria. Two indications were added, Psoriatic Arthritis and Ankylosing Spondylitis. • Dr. Burke asked if these have been added due to newly approved indications. Anne stated that these are FDA approved indications.	
2. Public Comment	• No public comment.	
3. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Schewe and seconded by Dr. Bryant to accept the SRS recommended criteria. The motion passed unanimously by roll call.
E. Discussion/Approval of PDL and Resulting PA Criteria for Non-preferred Drugs **1. New Urinary Incontinence Drugs – Darifenacin (Enablex®)**		
a. PDL Advisory Committee Recommendations	• Dr. Burke clarified that the PDL Committee focused its review on the newly release Urinary Incontinence (UI) drug. Dr. Burke stated that the PDL Committee determination was that all formulations of Urinary Incontinence Drugs are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Tolterodine LA (Detrol LA®), Oxybutynin (Ditropan®), Solifenacin Succinate (VESIcare®), and Darifenacin (Enablex®) to be preferred Urinary Incontinence drugs, and PA required for Flavoxate HCl (Urispas®), Oxybutynin XL (Ditropan XL®), Tolterodine (Detrol®), Oxybutynin Patches (Oxytrol®), and Trospium Chloride (Sanctura®). This will be effective in approximately October of 2005.	
c. Public Comment	• No public comment.	
d. Discussion	• Dr. Burke explained the PDL PA process to the new members. The DUR Boards job is to decide if the non-preferred PA criteria is acceptable. The DUR Board does not decide what is preferred and non-preferred.	
e. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Waite and seconded by Mr. Wilcox to accept the SRS recommendation for

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New Urinary Incontinence Drugs – Con't		Tolterodine LA (Detrol LA®), Oxybutynin (Ditropan®), Solifenacin Succinate (VESIcare®), and Darifenacin (Enablex®) to be preferred Urinary Incontinence drugs, and PA required for Flavoxate HCI (Urispas®), Oxybutynin XL (Ditropan XL®), Tolterodine (Detrol®), Oxybutynin Patches (Oxytrol®), Trospium Chloride (Sanctura®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
2. New Oral Bisphosphonates Ibandronate Sodium (Boniva®) **a. PDL Advisory Committee Recommendations**	• Dr. Burke clarified that the PDL Committee focused its review on the newly release Oral Bisphosphonate. Dr. Burke stated that the PDL Committee determination was that all formulations of Oral Bisphosphonates are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Alendronate (Fosamax®) and Risedronate (Actonel®) to be preferred Oral Bisphosphonates, and PA required for Ibandronate Sodium (Boniva®).	
c. Public Comment	• Barbara Reichenau (Hoffman-LaRoche) presented information to the DUR board regarding Boniva® with regards to nursing home patients.	
d. Discussion	• Dr. Waite pointed out that Bisphosphonates is misspelled on the PA form. • Mary pointed out that most of the dual eligible patients in the nursing homes will change over to Medicare Part D in January 2006, so this will only effect them for a couple of months.	
e. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Waite and seconded by Dr. Bryant to accept the SRS recommendation, with the correction of the spelling of Bisphosphonates on the PA form, for Alendronate (Fosamax®) and Risedronate (Actonel®) to be preferred Oral Bisphosphonates, and PA required for Ibandronate Sodium (Boniva®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.

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3. Insulins (Re-review) **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee reviewed the insulin delivery systems in 2003, all delivery systems were found to be clinically equivalent and multi vials became the preferred delivery system. The insulins were never reviewed until the June PDL meeting and the determination was that all formulations of insulins are clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the multi dose vials will continue to be the preferred delivery system, and PA required for pens and cartridges. We updated the form, previously the Humulin, Novolin, and Velosulin products were not listed	
c. Public Comment	• No public comment.	
d. Discussion	• Dr. Waite suggested adding Inolet delivery systems to the PA. Mary stated that she would add Inolet to the PA as non-preferred. • The board discussed the wording on the PA, Absence of delivery system, is confusing. Dr. Waite recommended changing the wording to Necessity of alternative delivery system.	
e. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Bryant and seconded by Dr. Grauer to accept the SRS recommendation, with the change of Absence of delivery system to Necessity of alternative delivery system and the addition of Inolet to the non-preferred delivery systems, for the multidose vials to be the preferred delivery system, and PA required for syringes, cartridges, inolets, and other alternative delivery systems with PA criteria of Necessity of alternative delivery system. The motion passed unanimously by roll call.
4. Sedative/Hypnotics (Re-Review) **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee originally reviewed the Sedative/Hypnotics in 2003 and found clinical equivalence. With the release of Lunesta® the PDL Committee re-reviewed this class and the determination was that all formulations of Sedative/Hypnotics are clinically equivalent.	

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Sedative/Hypnotics – Con't **b. SRS Proposal for Preferred Drugs and PA Criteria**	• Mary stated that the recommendation from SRS is for Zolpidem Tartrate (Ambien®) and Eszopiclone (Lunesta®) to be preferred Sedative/Hypnotics, and PA required for Zaleplon (Sonata®).	
c. Public Comment	• No public comment.	
d. Discussion	• No board discussion.	
e. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Mr. Wilcox and seconded by Dr. Schewe to accept the SRS recommendation for Zolpidem Tartrate (Ambien®) and Eszopiclone (Lunesta®) to be preferred Sedative/Hypnotics, and PA required for Zaleplon (Sonata®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
5. ACE/Calcium Channel Blockers (CCB) **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL committee has determined clinical equivalency in ACE Inhibitors and CCB separately. This particular class only includes three products with the indication for hypertension. The PDL Committee determination was that all formulations of ACE/CCB are clinically equivalent for the treatment of hypertension, with recommendation to generic substitution of individual components when available.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Amlodipine Besylate/Benazepril HCL (Lotrel®) to be preferred, and PA required for Enalapril Maleate/Felodipine (Lexxel®) and Trandolapril/Verapamil HCL (Tarka®).	
c. Public Comment	• No public comment.	
d. Discussion	• Dr. Schewe questioned why the PA criteria stated generic equivalents under the list of drugs. Karen stated that is for when new generic products are released.	
e. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Schewe and seconded by Dr. Kentfield to accept the SRS recommendation for Amlodipine Besylate/Benazepril HCL (Lotrel®) to be preferred ACE/CCB, and PA required for Enalapril Maleate/Felodipine (Lexxel®) and Trandolapril/Verapamil HCL (Tarka®) with PA criteria

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ACE/CCB – Con't		of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
6. Anti-Virals – Reviewed Agents are All Preferred **a. PDL Advisory Committee Recommendations** **b. SRS Proposal for Preferred Drugs and PA Criteria**	• Dr. Burke stated that the PDL Committee determination was that all formulations of Anti-Virals are clinically equivalent. • Mary stated that the PDL Committee reviewed Acyclovir (Zovirax®), Valacyclovir (Valtrex®), and Famciclovir (Famvir®). SRS's recommendation is for all of these to be on the Preferred Drug List, so there is no PA form to approve.	
7. Glaucoma Agents – Ophthalmic Prostaglandin Analogs **a. PDL Advisory Committee Recommendations** **b. SRS Proposal for Preferred Drugs and PA Criteria** **c. Public Comment**	• Dr. Burke stated that the PDL Committee determination was that there is clinical equivalence among Latanoprost (Xalatan®), Bimatoprost (Lumigan®), and Travaprost (Travatan®); Unoprostone (Rescula®) is not as efficacious as the others in the class. • Mary stated that the recommendation from SRS is for Travoprost (Travatan®) to be preferred Glaucoma Agents – Ophthalmic Prostaglandin Analogs, and PA required for Latanoprost (Xalatan®), Bimatoprost (Lumigan®), and Unoprostone (Rescula®). • Jim Baumann (Pfizer) presented information to the DUR Board regarding Xalatan®. Mr. Baumann pointed out that 80%-90% are currently on Xalatan® and Lumigan®. By including Xalatan® and Lumigan® on the non-preferred list this could have a cost impact on the PA unit and in the medical costs due to office visits. Mary stated that there will be no cost impact in the PA unit and the state did take into consideration the medical expenses. Mr. Baumann pointed out that 65%-70% are 65 or older, so they will move to Medicare Part D the beginning of January 2006. Would like to recommend either delaying the implementation date of this PA or grandfathering the current beneficiaries receiving Xalatan®.	

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Glaucoma Agents – Ophthalmic Prostaglandin Agents – Con't	• Dr. Burke asked Mary what the effective date for this PA would be. Mary stated that it would be the beginning of October, but it could take longer. • Mary stated that even though most dual eligible beneficiaries are 65 and older and will move to Medicare Part D, we still have to consider our patients who are not dual eligible. Mary stated that she spoke to numerous physicians who said they would recheck patients pressure 6/8 weeks after the beneficiary has been changed to the new drug and most stated they use Travatan® as first line. They believe Xalatan® is highly prescribed due to Xalatan® being the fist agent in this class. At this time we don't know what the Prescription Drug Plan (PDP) will place on the formulary for Medicare Part D. Mr. Baumann stated there is a chance the dual eligible patients will have to change to Travatan® and then change again if Travatan® is not on the Medicare Part D formulary. Mary pointed out that this class of drugs is clinically equivalent, there should not be an issue with changing drugs. • Eric Byrnes (Alcon) presented information to the DUR Board regarding Travatan®. The VA chose Travatan® as their preferred agent in this class and they have had no issues with this change. 49 state Medicaid programs have Travatan on the PDL without any issues.	
d. Discussion	• Dr. Burke informed the Board that their responsibility is to decide if the PA form is acceptable, not to change preferred and non-preferred agents. Dr. Burke stated that he had a letter from the VA stating there were no problems with there transition to Travatan®. • Dr. Grauer asked if we were going to consider changing the implementation date. Mary stated that she probably would not change the implementation date. We should have information on the PDP formulary by September. • Dr. Burke asked how easy it would be to grandfather the current patients that are dual eligible. Karen stated that would not be easy to identify dual eligible patients; there would be additional cost due to system changes. • Mary stated that we could exempt 65 and up from the PA process. Dr. Burke asked if that is automated. Karen stated that it is.	

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Glaucoma Agents – Ophthalmic Prostaglandin Agents – Con't **e. DUR Board Recommendations**	• Dr. Kentfield stated that in LTC setting most physicians won't schedule an appointment to change from one Ophthalmic Prostaglandin Analog to another, they will change the script when called by the pharmacy. This will be mostly an administrative cost issue, wouldn't recommend delaying implementation for this issue. Dr. Burke asked if the doses are the same. Dr. Kentfield stated they are the same, if the dosing were different an office visit might be required. • With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Unruh and seconded by Dr. Waite to accept the SRS recommendation for Travoprost (Travatan®) to be preferred Glaucoma Agents – Ophthalmic Prostaglandin Analogs, and PA required for Latanoprost (Xalatan®), Bimatoprost (Lumigan®), and Unoprostone (Rescula®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion passed with Dr. Grauer voting no and the rest voting yes.
F. Additional Announcements	• Dr. Burke complemented Heritage regarding the June 2005 DUR newsletter. He was a little confused about the statement, generic equivalents, that is stated under the preferred and non-preferred drugs. Thought all generics were preferred agents. Mary stated that is not necessarily true. We place this statement on the PDL in case a generic is released, it will automatically be included on the preferred or non-preferred without having to be re-reviewed. • Anne announced that Erica Miller is moving to Kansas City, this is her last meeting.	
V. Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Unruh and seconded by Dr. Bryant to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:40 a.m.